

**REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**I. DISPOSITION OF CLAIMS; SUPPORT FOR AMENDMENT**

After amending the claims as set forth above, claims 1, 14, 17-22, and 33-34 are under examination. Claims 1, 14-23, and 26-34 are pending. Claims 15-16, 23 and 26-32 have been withdrawn as non-elected.

Claim 1 is currently being amended to further define the “vegetable and/or mineral oil” and the “lipophilic additive”. Dependent claims 14 and 19 have been correspondingly amended.

The amendment adds no new matter. The amendment is supported by the specification at page 4, lines 8-20, and page 5, lines 24-27.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

**II. REJECTION UNDER 35 USC §103(A) (OBVIOUSNESS)**

The claims stand finally rejected as obvious over of the combination of US 5,273,754 (“Mann”), US 2002/0192308 (“Mamana”), and JP 2001064672 (“Hosoya”).

Applicant has obviated this ground of rejection by amending the claims to require “soya oil, sunflower oil, corn oil, olive oil, nut oil, [or] a liquid paraffin” and “polyethylene glycol, beeswax, candelilla wax, carnauba wax, polyethylene oxide wax, petroleum wax, [or] glycerol palmitostearate”.

The claims as amended are nonobvious over Mann, Mamana, and Hosoya because, *inter alia*, Hosoya is silent regarding diminishing the irritant effect of capsaicinoids, Mann discloses unrelated “essential oils” (i.e., menthol), and Mamana’s soya based meal replacement lacks soya oil.

Applicant's arguments do not attack the cited references individually. Instead, Applicant points out herein where the Office's assertions are inaccurate regarding the cited references and how the cited references are deficient in establishing a prima facie case of obviousness for the claims as presently amended.

**A. Mann Fails To Disclose Any Of The Claimed Oils**

The present amendment more clearly renders irrelevant the Mann reference, on which the Office relied for disclosure of "peppermint, menthol, and spearmint" as alleged vegetable oils. The Office stated as follows (emphasis added; Office Action, page 3, lines 1-5):

Mann teaches an appetite suppressant leading to a decrease in weight (col 1, lines 5-10) comprising a heating carminative substance, such as standard oleoresin capsicum which contains capsaicin (thus capsaicinoids) (thus in the form of capsicum resin) (col 2, lines 45-50), and a cooling carminative substance selected from peppermint, menthol, and spearmint etc (thus contains a vegetable oil) (claim 3 ; example 2).

This disclosure is not relevant to the claims as amended, wherein "vegetable and/or mineral oil" has been replaced with "soya oil, sunflower oil, corn oil, olive oil, nut oil, and a liquid paraffin". "Peppermint, menthol, and spearmint" are not equivalent to nor suggestive of soya oil, sunflower oil, corn oil, olive oil, nut oil, or a liquid paraffin.

For the record, Applicant notes that Peppermint (*Mentha X piperita*) and Spearmint (*Mentha spicata*) do not contain any "oil" as mono-, di- or triglycerides of fatty acids but only totally different substances which are the so-called "essential oils", e.g. esters (menthyl acetate), free alcohols (menthol) and ketones (menthone). See German Commission E monographs for "Peppermint leaf" and "Peppermint oil" and Rios-Estepeda et al., PNAS, Vol. 105(8), pp. 2818-2823 (2008) (each submitted herewith in an Information Disclosure Statement). The monographs and Rios-Estepeda disclose that peppermint oil contains esters (menthyl acetate), free alcohols (menthol), and ketones (menthone). Therefore Mann discloses no "vegetable oil" but instead discloses "essential oil" which is chemically totally different. The present claims do not mention any "essential oil".

**B. Hosoya Discloses No “Solid Or Pasty” Formulation And Is Unrelated To Reducing Irritant Effect Of Capsaicinoids**

Applicant has provided an English translation of Hosoya (submitted in an Information Disclosure Statement).

The Office stated as follows (emphases added; Office Action, paragraph bridging pages 3-4):

Hosoya et al teach a fat metabolizer ingested (thus acceptable for oral administration) in very small amount comprising fats and oils consisting of diglyceride and/or monoglyceride, triglyceride (thus a lipophilic additive, solid or pasty at room temperature), linseed oil (thus a vegetable oil) etc. Hosoya et al also teach that the obtained fats and oils filled in a soft capsule (thus solid or pasty at room temperature).

Based on the English translation of Hosoya, the Office erred in concluding that the Hosoya preparation is solid or pasty at room temperature. Hosoya states as follows (emphases added; see paragraph [0015] bridging pages 8-9):

[0015] When the body fat combustion promoter of the present invention is used as pharmaceuticals, the dosage form includes oral, enteral and intravenous administrations, and pharmaceuticals for oral administration are preferred. Specific examples of the dosage form include solid preparations such as powders, granules, capsules, pills and tablets; and liquid preparations such as solutions, suspensions and emulsions.

Here, Hosoya distinguishes “solid preparations” for capsules from “liquid preparations”. In Hosoya, “capsules” are mentioned in the meaning of hard shell capsules containing a powder, which is solid (not pasty) dosage form at room temperature but also solid at high temperature; in such a formulation, specific oil prepared by Hosoya would be fixed on adsorbent powder.

Claim 1 as amended requires specific lipophilic additives that are solid or pasty at room temperature but that are liquid at 40 °C and above. The recited lipophilic additives “polyethylene glycol, beeswax, candelilla wax, carnauba wax, polyethylene oxide wax, petroleum wax, and glycerol palmitostearate” would not remain solid at high temperature. In addition, in the present invention, the mixture is suitable for filling soft gel capsules, which is a dosage form able to contain liquid, suspension or semisolid filling (see “Definition and

Characteristics” on pages 1-2 of the attached reference Y. Naguib, “Soft Gel Capsules”, Supplement Industry Executive, submitted herewith in an Information Disclosure Statement).

It is erroneous to conclude that, because Hosoya’s product is filled in a soft capsule, this serves as evidence that Hosoya satisfies “solid or pasty at room temperature”. To the contrary, Hosoya dosage form is certainly liquid in soft capsules at room temperature for two reasons. First, there is absolutely no information in this patent about use of any additive increasing viscosity. Second, Hosoya prefers a liquid preparation of reduced viscosity (emphasis added; see paragraph [0010]):

[0010] Particularly preferred composition of the oil or fat used in the present invention is shown. Regarding the diglyceride and/or monoglyceride, in view of decrease in viscosity and oxidation stability, the content of the  $\omega$ 3-based unsaturated acyl groups is preferably 15% or more, more preferably from 20 to 70%, and particularly preferably from 25 to 65%.

Accordingly, the Office erred in concluding that Hosoya discloses a lipophilic additive that is solid or pasty at room temperature

**C. Mamana’s Soya Based Meal Replacement Lacks Soya Oil**

Contrary to the Office’s assertion, Mamana does not disclose a formulation containing soya oil. The Office stated as follows (emphasis added; Office Action, page 3, lines 13-16):

Mamana teaches an appetite suppressant for controlling weight comprising green tea or green tea leaf extract (thus one or more physiologically active components) (claim 1). Mamana also teaches a method of controlling weight by replacing at least one meal with a soya based meal replacement (claim 22) (thus contains soya oil, a vegetable oil).

Soy based meal replacements lack soy oil. Such meal replacements are generally presented as powder to be diluted in water or milk to be eaten as replacement of a meal. The benefit of such product is to avoid the amount of fat and quickly metabolized carbohydrates present in a normal meal, as meal replacements mainly contain proteins and slowly metabolized carbohydrates. Meal replacements have different compositions from “normal” meals, the major constituents of meal replacements being milk proteins or soya proteins, both of them being defatted.

In support of these assertions, Applicant has submitted herewith in an Information Disclosure Statement the references Aoyama et al., Biosci. Biotechnol. Biochem., Vol. 64(12), pp. 2594-2600, 2000 and “Soy Protein Isolates – Specification” by Can Am Ingredients, Inc.

Aoyama discloses in table 1 (page 2595) formulations wherein each formulation contains 5 % of fat that is entirely due to 5 % of added soybean oil. Formulations with and without soy protein have identical fat level of 5 %, which proves that the soy protein used in soy meal replacements contains no soy oil.

The “Soy Protein Isolates” reference states that the fat content is “Max. 0.5%”, thus confirming that soy protein lacks soy oil.

Therefore, the Office erred in finding that soy based meal replacement contains soya oil.

**D. Comparative Data Is Unnecessary Because Applicant’s Invention Relates To Reducing Capsaicinoid Irritation, Not Weight Reduction**

Applicant’s discovery is necessarily unexpected because it was unknown. None of the cited references suggests reduction of capsaicinoid-based gastric irritation by any components in the presently claimed formulation.

The Office asserted that “Applicant needs to present a side by side comparison between the claimed invention and the closest art to show the allegedly surprising results” (Office Action, sentence bridging pages 6-7).

Applicant respectfully submits that no “side by side comparison” is necessary, because the invention does not relate to synergistic effect on weight control.

The present invention is not dealing with increased efficacy of weight control, but instead relates to protection against burning effect on stomach of capsaicinoids, due to the combination of components, including the recited oils/paraffin and specific amounts of recited lipophilic additives.

The specification discloses the results of "Digestive Tolerance Tests on Healthy Subjects" demonstrating that the invention provides a surprising improvement in the reaction of human subjects to capsicum (page 11, line 9, et seq.).

Accordingly, even if a prima facie case of obviousness were properly made out, which Applicant denies as explained herein, such a prima facie case would be effectively rebutted by the unexpected results disclosed in present specification.

For all the reasons provided above, the obviousness objection should be withdrawn.

**CONCLUSION**

Applicant requests entry of this Amendment because it raises no new issues, would require no further search, and would place the application in condition for allowance.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

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